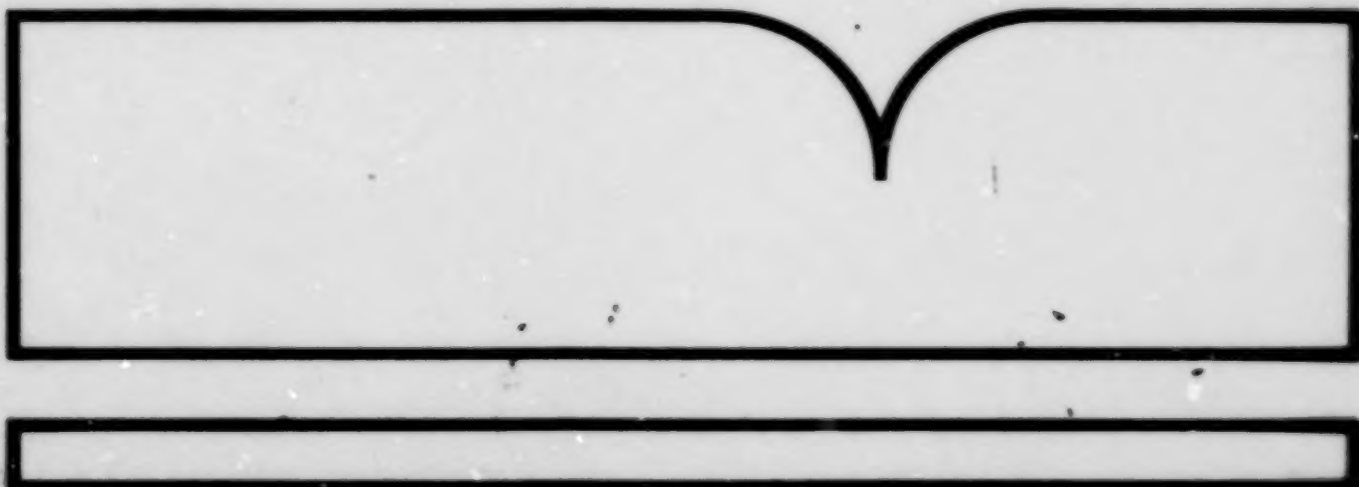


PB85-144814

Guidance for the Reregistration of
Manufacturing-Use and Certain End-Use
Pesticide Products Containing Diallate

(U.S.) Environmental Protection Agency
Washington, DC

31 Mar 83



GUIDANCE FOR THE
REREGISTRATION OF MANUFACTURING-USE
AND CERTAIN END-USE PESTICIDE PRODUCTS
CONTAINING
DIALATE

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

WASHINGTON, D.C. 20460

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this document and are not included.

I. Introduction

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth the requirements for registration and reregistration of all manufacturing-use products (MUPs) containing the subject chemical as the sole active ingredient. These requirements are: that certain scientific data be submitted; that certain standards of toxicity, composition, labeling, and packaging be met; and that the data compensation provisions of FIFRA Section 3(c)(1)(D) be satisfied. Registrants of MUPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements and compensation responsibilities for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA, (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, IV and VII and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the times outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

II. Regulatory Position and Rationale

A. Introduction

This chapter presents the regulatory position of the Environmental Protection Agency, hereafter referred to as "the Agency," on all registered manufacturing-use products (MUPs) containing diallate as the sole active ingredient. Future requests for registrations of substantially similar products will be covered by this standard. Dissimilar products will require amendments to the standard. This document provides the rationale for the Agency's position and the criteria for registration. It also discusses labeling requirements.

B. Use Profile

Diallate is a thiocarbamate herbicide used to control wild oats in certain crops. Principal use sites are sugar beets, flax, lentils and dry peas. Other registered sites include barley, corn, forage, legumes (alfalfa and clover), potatoes and soybeans. The estimated total active ingredient used annually is confidential under FIFRA Sections (7) and (10). However, 60 percent of the total annual usage is applied to the sugar beets. Diallate usage is confined almost exclusively to the geographical area extending from Minnesota to the Pacific Ocean and south into California, Utah and Wyoming.

C. Background

Diallate is the accepted common name, recognized by the International Organization for Standardization and the British Standard Institution. Its chemical name is S-(2,3-dichloroallyl)-N,N-diisopropylthiocarbamate. The other trade names by which diallate is known are Avadex, DATC and CP 15336. The Office of Pesticide Programs Internal Control Number (EPA Shaughnessy number) is 078801. Diallate was developed and introduced in 1961 by the Monsanto Company under the code name CP 15336 and the trade name Avadex. It was patented under USP 3,330,643.

The technical material is manufactured in Belgium by the Monsanto Company. It is imported into the United States from Belgium by the Monsanto Company, St. Louis, Missouri.

Technical diallate is shipped as a manufacturing-use product. There are two formulations: an emulsifiable concentrate (EC) containing 4 lb active ingredient/gallon and a 10% granular. The EC is registered for all sites while the granular is registered only for use on sugar beets. A multiple active ingredient product, Dexil, containing diallate and pebulate is also registered for use on sugarbeets.

D. Regulatory Position

Based on a review and evaluation of all available data and other relevant information, the Agency has made the following determinations:

1. Both currently registered and new manufacturing-use pesticide (MUP) products containing diallate as the sole active ingredient may be reregistered or registered for sale, distribution and use, subject to

the terms and conditions specified within the guidance document. Applicants having products not conforming to this guidance document must apply to amend the document so those products containing diallate may be registered and reregistered under this guidance package. Mixtures and end-use products containing diallate may not be registered and reregistered under this guidance package. However, the use patterns of the end-use products are considered for purposes of determining generic data requirements for diallate.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of diallate, as long as product labels reflect the restrictions imposed in this standard. The potential oncogenicity of diallate was addressed and resolved in a recent RPAR review (FR Notice 47, 27109, June 23, 1982).
3. Registrants must provide or agree to develop the data specified in the tables within this guidance package in order to maintain existing registrations.
4. Applications of the pesticide diallate made in accordance with current use directions are not expected to result in residues of diallate in excess of 0.05 ppm (negligible residue) (which is the established tolerance for all listed crops) for alfalfa (fresh and hay), barley, grain, forage grain, fodder and forage, flaxseed, lentils, peas, pea forage and hay, potatoes, safflower seed, soybeans, soybean forage and hay, and sugar beet roots and tops. Diallate is rapidly absorbed and metabolized by plants to CO₂ and other naturally occurring plant organic products; no diallate residues have been found in plants at harvest. Therefore, no metabolites have been included in the tolerance. Similarly, no tolerances have been set for diallate or its metabolites in milk, meat or meat byproducts because no diallate residues are expected in feed. For the same reasons, no storage stability data are required.

E. Regulatory Rationale

1. The Agency has reviewed the available toxicology data for diallate. Sufficient data are available to show that technical diallate and manufacturing-use product diallate have low oral, dermal, primary eye and dermal irritation toxicity. Therefore, technical and manufacturing product are classified under toxicity category III. Acute inhalation data are not available for review so it is considered a data gap for technical and MUP's. Acute delayed neurotoxicity data are waived because subchronic neurotoxic data have been requested which will fulfill the acute neurotoxicity data gap.

Because no chronic feeding studies are available, these tests are required in two species, a rodent and a non-rodent. Similarly, teratogenicity studies in two species are also required.

Oncogenicity data on the hamster submitted by the Monsanto Company have been reviewed and evaluated by the Agency. The histopathological examination identified an increase in both benign and malignant lesions. During the RPAR review, the Agency determined the potential oncogenic risk to humans, but concluded that the levels of risk will

be acceptable as long as protective clothing is worn and use is restricted to certified applicators only. The three-generation reproduction study has been carried out on male and female rats at dietary concentrations of up to 100 ppm. No treatment-related abnormalities were observed. All available mutagenicity studies were reviewed by the Agency. The Agency concluded that diallate has potential for mutagenic activity in several species of microorganisms and in cultured mammalian cells. These studies only partially fulfill requirements for mutagenicity data. Since the studies indicated positive mutagenic activity, additional studies have been requested. The required studies are in vitro cytogenesis or micronucleus tests and dominant lethal tests, both in rodents. The Agency has adequate information on metabolism, so no additional information is necessary.

2. The available diallate environmental fate data are insufficient to fully assess this chemical at this time. The only data available were aerobic soil metabolism studies, which were determined to be anaerobic soil metabolism, leaching (and adsorption/desorption), field soil dissipation and accumulation in fish. Reentry data are waived because diallate is incorporated into the soil and degrades fairly rapidly. Therefore, exposure to workers reentering the field is expected to be minimal. Also, there have been no incidents reported under the Pesticide Incident Monitoring System. There are no state or Federal reentry intervals for diallate.
3. The only available study on the ecological effects of technical diallate is an acute contact LD₅₀ on honey bee which shows no hazard. The Agency is requiring an avian oral LD₅₀ and dietary LC₅₀. In addition, the LC₅₀ studies on fresh water fish and invertebrates will be required.
4. Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that tolerances be established for any pesticide residues in raw agricultural commodities which are grown with the use of such pesticide. Therefore, the Agency has established tolerances of diallate at negligible residues of 0.05 ppm on or in the commodities listed earlier. Section 409 of FFDCA requires that the tolerance established for any pesticide residues concentrating in processed food in levels higher than the tolerances set for the raw commodities. However, the Agency has determined that diallate is a short life pesticide which breaks down to naturally occurring products; therefore, no residues are expected in processed food/feed and there is no need to establish such tolerances.

The Agency has established that the applications made in accordance with current labels are not expected to result in residues of diallate in the commodities described earlier in excess of 0.05 ppm (negligible residues).

5. Nitrosamines are present in diallate at levels below 1 part per million. The Agency's policy is that pesticides with 1 ppm or less of N-nitroso compounds will be treated under the usual registration procedures (45 FR 42854), unless the Agency is especially concerned about the nitrosamines present, and therefore products containing diallate will be handled under normal registration procedures.

6. In accordance with the FIFRA, the Agency's policy is not to cancel or to withhold registration merely for the lack of certain data (see sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, publication of this guidance package provides a mechanism for identifying data needs, and reregistration under this document allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of diallate.

F. Criteria for Registration Under this Standard

All products which contain diallate as the sole active ingredient and an active ingredient in a mixture are subject to this standard and must either comply with the acute toxicity limits, product composition, and use patterns requirements listed in Section G of their document, or submit data and a justification to amend the standard to encompass such products.

The Applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including committing to fill data gaps on a schedule agreed to by both this agency and the applicant, and, when applicable, offering to pay compensation for data to the extent required by Section 3(c)(1)(D) of the FIFRA. Applicants for registration under this standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

G. Acceptable Ranges and Limits

1. Product Composition Standard

For manufacturing-use products to be eligible for registration/reregistration under this standard, technical products and manufacturing-use products must contain at least 95 percent diallate as the sole active ingredient. Each product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the MUP diallate products must be substantially similar to that in currently registered technical products. Any MUP not meeting these requirements will be considered a new product and will require an amendment to the standard.

2. Acute Toxicity Limits

The Agency will consider registration/reregistration of manufacturing-use products containing diallate of the toxicity categories III and IV if the labeling of such products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing diallate must be labeled to allow for formulation only into

end-use products, which are intended for terrestrial food and terrestrial non-food crop uses, which includes alfalfa (fresh and hay), barley (grain, forage, and straw), clover (fresh and hay), field corn grain, fodder and forage, flaxseed, lentils, peas, pea forage and hay, potatoes, soybeans, soybean forage and hay, and sugar beet roots and tops.

H. Required Labeling

All manufacturing-use products containing diallate must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of this guidance package contain specific information regarding label requirements.

In addition, the following specific labeling requirements apply to technical and manufacturing-use products:

1. Use Pattern Statement

For formulation into end-use insecticide/herbicide products intended only for terrestrial food and terrestrial non-food crop uses.

2. Human Hazard Precautionary Statements

Cause cholinesterase inhibition. Atropine is antidotal. 2 PAM is also antidotal and may be administered in conjunction with atropine. Warning symptoms of cholinesterase inhibition include weakness, headache, tightness in the chest, blurred vision, nonreactive pinpoint pupils, salivation, sweating, nausea, vomiting, diarrhea and abdominal cramps.

The registrant may submit an alternative antidote statement for Agency consideration.

3. Environmental Hazard Statements

Do not discharge into lakes, streams, ponds, or public water unless in accordance with an NPDES permit. For guidance contact your Regional Office of the United States Environmental Protection Agency.

I. Tolerance Reassessment

There is no need to reassess tolerances at this time. All tolerances for diallate are set at 0.05 ppm (negligible residues) in or on the raw agricultural commodities described in Section D-4 under regulatory position. However, additional data would be required if a registrant should wish to:

- a. Establish a crop group tolerance for non-grass animal feeds, or
- b. Establish a crop group tolerance for the foliage of legume vegetables (additional data required) or change the label to identify and limit specifically the legume crops of barley-legume and flax-legume mixtures to those legumes with established tolerances.

III. Data Compensation

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

- A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).
- B. A statement acknowledging that if EPA approves your application for registration for registration, the approval will be based on EPA's consideration of the following:
 1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing-Use and End-Use Products" (Table A at the end of Section IV), are relevant to EPA's evaluation of the registrability of your product.
 2. For the manufacturing use products, the "product-specific" data** which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).
- C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:
 1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product specific data upon which approval of your application will be based, except that:
 - a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

* Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

** Product-specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

- b. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography (Appendix III-3) who have not waived their rights to receive offers will be listed in Tables A and B (MUP registrants are referred to both Tables A and B; end-use product registrants are referred to only Table A). You will be required to write the companies listed in the appropriate table(s) if the data in those tables are required to support your formulations and/or uses.
 - c. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.
 - d. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.
2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:
- a. A notification of your intent to apply for registration or reregistration under this guidance document, and the name, active ingredient, and intended use of your product.
 - b. An offer to pay the person compensation with respect to approval of your application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.
 - c. Your name, mailing address, and telephone number.

**IV. Requirement for Submission of Generic Data Under FIFRA
Section 3(c)(2)(B)**

- A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

- B. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, the Pesticide Registration Guidelines*, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section V of this document.

- C. Options Available for Complying with Requirements to Submit Data.

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA §3(c)(2)(B) Summary Sheet" [Appendix IV-2(a)] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and (b) either submit

* The Pesticide Registration Guidelines were repropoed on November 24, 1982 in 47 Federal Register 53192.

the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must notify EPA which registrant(s) are parties to the agreement.
3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" (Appendix IV-3.)*
4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)
5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for products.)

* FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is unable to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.120 Product Chemistry</u>				
<u>Product Identity:</u>				
61-2 - Statement of Composition	TGAI	Yes	CS-0098-019 CS-0098-020 CS-0098-021 CS-0098-022 CS-0098-023	No
61-3 - Discussion of Formation of Ingredients	TGAI	Yes	00086417	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis	TGAI	No	-	Yes
<u>Physical and Chemical Characteristics</u>				
63-2 - Color	TGAI	Yes	CS-0098-020 00086414 00086391	No
63-3 - Physical State	TGAI	Yes	CS-0098-024 00086414 00086392	No
63-4 - Odor	TGAI	No	-	Yes

^{1/} Composition: TGAI = technical grade of the active ingredient.

^{2/} Data must be submitted no later than 6 months.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLABE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>§158.120 Product Chemistry (continued)</u>				
63-6 - Boiling Point	TGAI	Yes	GS-0098-023 GS-0098-024 00086414 00086391	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	GS-0098-024 00086414 00086391	No
63-8 - Solubility	TGAI OR PAI	Partial ^{3/}	GS-0098-020 GS-0098-023 00086414	Yes
63-9 - Vapor Pressure	TGAI OR PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	No	-	Yes
63-13 - Stability	TGAI	Yes	GS-0098-024 00086414 00086391	No
<u>Other Requirements:</u>				
64-1 - Submittal of samples	Choice	No	-	Deferred ^{4/}

- ^{1/} Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
^{2/} Data must be submitted no later than 6 months.
^{3/} The solubility of diallate in several solvents has been identified. But quantitative data are not given.
^{4/} The Agency may request samples at a future date.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.135 Toxicology</u>					
<u>ACUTE TESTING:</u>					
81-1 - Oral LD ₅₀ - Rat	TGAI	A, B	Yes	00086378 00086441	No
81-2 - Dermal LD ₅₀	TGAI	A, B	Yes	00050737 00086379 00050737	No
81-3 - Inhalation LC ₅₀ - Rat	TGAI	A, B	No	-	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A, B	No	-	No ^{4/}
<u>SUBCHRONIC TESTING:</u>					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A	No	-	No ^{5/}
82-2 - 21-Day Dermal	TGAI	A, B	No	-	No ^{6/}
82-3 - 90-Day Dermal	TGAI	A, B	No	-	No ^{6/}
82-4 - 90-Day Inhalation - Rat	TGAI	A, B	No	-	Deferred ^{7/}
82-5 - 90-Day Neurotoxicity - Hen/Mammal	TGAI	A, B	No	-	Yes

^{1/} Composition: TGAI = Technical grade of the active ingredient.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data must be submitted within 48 months.

^{4/} Further acute neurotoxicity testing is not required. See 90-day neurotoxicity testing need.

^{5/} Additional 90-day feeding studies will not be required if 2-year feeding studies are submitted.

^{6/} Waiver because of low dermal toxicity.

^{7/} The determination of requirement for a 90-day inhalation study is deferred until results of the acute inhalation study have been evaluated.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.135 Toxicology (continued)</u>					
<u>CHRONIC TESTING:</u>					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A	No	-	Yes ^{4/}
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A, B	Yes	GS-0098-015	No
83-3 - Teratogenicity - 2 species	TGAI	A, B	No	-	Yes
83-4 - Reproduction, 2-generation	TGAI	A	Yes	00028956	No
<u>MUTAGENICITY TESTING:</u>					
84-2 - Gene Mutation	TGAI	A, B	Yes	05011869 05012173 GS-0098-006 GS-0098-014 05018683 05011877 GS-0098-002 GS-0098-016 GS-0098-017	No

^{1/} Composition: TGAI = Technical grade of the active ingredient.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data must be submitted within 48 months.

^{4/} Required in two species for all uses requiring a tolerance.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.135 Toxicology</u> (continued)					
84-2 - Chromosomal Aberration	TGAI	A, B	Yes	GS-0098-006	No
84-2 - Other Mechanisms of Mutagenicity	TGAI	A, B	Partial	GS-0098-006 GS-0098-013 0501683	Yes ^{4/}
<u>SPECIAL TESTING:</u>					
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00073505	No

^{1/} Composition: TGAI = Technical grade of the active ingredient.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data must be submitted within 48 months.

^{4/} (a) Rodent in vitro cytogenesis or micronucleus test.

(b) Dominant lethal test in rodent.

If either or both are positive, consultation with the Agency is advised.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.140 Reentry Protection</u>					
132-1 - Foliar Dissipation	TEP	A, B	no	-	no ^{3/}
132-1 - Soil Dissipation	TEP	A, B	no	-	no ^{3/}
132-1 - Dermal Exposure	TEP	A, B	no	-	no ^{3/}
132-1 - Inhalation Exposure	TEP	A, B	no	-	no ^{3/}

^{1/} Composition: TEP = Typical end-use product.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data are waived since diallate is soil incorporated. There is a low potential for reentry exposure to workers, soil volatility is low and has a fairly short half life in soil.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.145 Wildlife and Aquatic Organisms</u>					
<u>AVIAN AND MAMMALIAN TESTING</u>					
71-1 - Avian Oral LD ₅₀	TGAI	A	no	-	yes
71-2 - Avian Dietary LC ₅₀	TGAI	A	no	-	yes
<u>AQUATIC ORGANISM TESTING</u>					
72-1 - Freshwater Fish LC ₅₀	TGAI	A	no	-	yes
72-2 - Acute LC ₅₀ Freshwater Invertebrates	TGAI	A	no	-	yes
72-3 - Acute LC ₅₀ Estuarine and Marine Organisms	TGAI	A	no	-	no ^{4/}

^{1/} Composition: TGAI = Technical grade of the active ingredient.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data must be submitted no later than 48 months.

^{4/} Would normally be required for corn use, except that use is limited to MN, MT, and ND.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.155 Nontarget Insect</u>					
<u>Nontarget Insect Testing- Pollinators</u>					
141-1 Honeybee acute contact LD ₅₀	TGAI	A	yes	00036935	no

^{1/} Composition: TGAI = Technical grade of the active ingredient.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data must be submitted no later than 48 months.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.125 Residue Chemistry</u> (Continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
- Meat, Milk, Poultry and Eggs	TCAI or Plant Metabolites	No	-	No ^{3/}
171-6 - Proposed Tolerances	EP	Yes	GS-0098-024 GS-0098-025 GS-0098-026 GS-0098-027 GS-0098-028 GS-0098-029	No

^{1/} Composition: TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than 48 months.

^{3/} Residue data on feeds do not indicate the need for a tolerance for animal products.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TGAI or PAIRA	A, B	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A, B	No	-	Yes
161-3 - On soil	TGAI or PAIRA	A, B	No	-	No ^{4/}
161-4 - In air	TGAI or PAIRA	A, B	No	-	No ^{4/}
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic soil	TGAI OR PAIRA	A, B	Yes	GS-0098-018	no
162-2 - Anaerobic soil	TGAI OR PAIRA	A, B	No	-	yes
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and Adsorption/desorption	TGAI or PAIRA	A, B	No	-	yes

- ^{1/} Composition: TGAI = technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled.
^{2/} The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
^{3/} Data must be submitted no later than 48 months.
^{4/} Since diallate is used exclusively as a herbicide for soil incorporation, photodegradation of diallate on soil and in air is minimal, so such data are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALLATE

Data Requirement	Composition ^{1/}	Use Patterns ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.130 Environmental Fate (Continued)</u>					
163-2 - Volatility (Lab)	TEP	A, B	No	-	No ^{4/}
163-3 - Volatility (Field)	TEP	A, B	No	-	No ^{4/}
<u>DISSIPATION STUDIES - FIELD:</u>					
164-1 - Soil	TEP	A, B	No	-	yes
164-5 - Soil, Long Term	TEP	A, B	No	-	Reserved ^{5/}
<u>ACCUMULATION STUDIES:</u>					
165-1 - Rotational Crops (continued)	PAIRA	A, B	no	-	yes
165-2 - Rotational Crops (continued)	TEP	A, B	no	-	no ^{6/}
165-4 - In Fish	TGAI or PAIRA	A, B	no	-	no ^{6/}

^{1/} Composition: TGAI = technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product..

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D-Aquatic, Non-Food; E-Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

^{3/} Data must be submitted no later than 48 months.

^{4/} Because diallate is used exclusively as a herbicide for soil incorporation, volatility is expected to be minimal.

^{5/} Reserved pending results of 164-1.

^{6/} Waived because aerobic soil metabolism shows low potential for accumulation in rotated crops.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/3/}
<u>\$158.125 Residue Chemistry</u>				
171-4 - Nature of Residue (Metabolism)	PAIRA	Yes	00086413 00086429 00021823 00086416 00086410 GS-0098-025 GS-0098-026 GS-0098-024	No
- Plants				
- Livestock	PAIRA and plant metabolites	No		No ^{3/}
<u>171-4 - Residue Analytical Method</u>				
- Plant Residues	TCAI and metabolites	Yes	05005967 05013158 05010424 00002536 05016141 00086389 05022018 00086421 05010440 05017611 05003572 05013076 00068699 05002512 05012983 05018944 05003776 05008924 05002372 05015190 00086429 GS-0098-030 00086390 GS-0098-025 00086425 GS-0098-028 00086433 GS-0098-026 00086416 GS-0098-024 00086410 GS-0098-029	No

^{1/} Composition: TCAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than 48 months.

^{3/} Diallate is rapidly and completely metabolized in plants to carbon dioxide and incorporated into naturally occurring plant constituents. Therefore there is no need for studies of the metabolism in animals, analytical methods and storage stability.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.125 Residue Chemistry</u> (Continued)				
171-4 - Residue Analytical Method (continued)				
- Animal Residues	TCAT and metabolites	No	=	No ^{3/}
171-4 - Storage Stability Data	FAI	No	-	No ^{3/}
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use				
- Crop Group #1 - Root and Tuber Vegetables Group				
o Crop 1 (Potatoes)				
- Crop Field Trials	TEP	Yes	GS-0098-026 GS-0098-024	No
- Processed Food/Feed	EP	No	-	No ^{4/}
o Crop 2 (Sugar Beets)				
- Crop Field Trials	TEP	Yes	GS-0098-026 GS-0098-024 00086432	No

1/ Composition: TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than 48 months.

3/ Diallate is rapidly and completely metabolized in plants to carbon dioxide and incorporated into naturally occurring plant constituents, therefore there is no need for studies of the metabolism in animals, analytical methods and storage stability.

4/ No residues are found on potatoes, therefore no residues are expected on the processed food/feed.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALIATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.125 Residue Chemistry</u> (Continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
- Processed Food/Feed	EP	No	-	No ^{3/}
- Crop Group #2 - (Leaves of Root and Tuber Vegetables Group)				
o Crop 1 (Sugar Beet Tops)				
- Crop Field Trials	TEP	Yes	GS-0098-026 GS-0098-024	No
- Processed Food/Feed	EP	No	-	No
- Crop Group #3 - Legume Vegetables (Stoculent or Dried)				
o Crop 1 (Lentils)				
- Crop Field Trials	TEP	Yes	GS-0098-026 GS-0098-024	No
- Processed Food/Feed	EP	Yes	GS-0098-026 GS-0098-024	No

1/ Composition: TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than 48 months.

3/ Since there are no detectable residues in sugar beets, no residues are expected in the byproducts - sugar, dried beet pulp and molasses.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.125 Residue Chemistry</u>				
(Continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
o Crop 2 (Peas)				
— Crop Field Trials	TEP	Yes	GS-0098-026 GS-0098-024	No
— Processed Food/Feed	EP	Yes	GS-0098-026 GS-0098-024	No
o Crop 3 - (Soybeans - Seed)				
o Crop 1 (Sugar Beet Tops)				
— Crop Field Trials	TEP	Yes	GS-0098-026 GS-0098-024	No
— Processed Food/Feed	EP	No	-	No ^{3/}
- Crop Group #4 - (Foliage of Legume Vegetables Group)				
o Crop 1 (Lentils) Forage and Hay				
— Crop Field Trials	TEP	Yes	GS-0098-024	No
— Processed Food/Feed	EP	No	-	No ^{4/}

^{1/} Composition: TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than 48 months.

^{3/} There are no detectable residues of diallate on soybeans, so there is no expectation that residues will be found in the byproducts - soybean meal, hulls, soapstock, and crude and refined oil.

^{4/} Pea forage data indicate that there are no detectable residues, so no residues are expected on peas.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.125 Residue Chemistry</u> (Continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
- Crop Group #7 - (Feeds - Forage, Fodder, Straw and Hay) Non-grass Animals				
o Crop 1 (Alfalfa - Fresh and Hay)				
— Crop Field Trials	TEP	Yes	GS-0098-024 GS-0098-026 GS-0098-028	No
— Processed Food/Feed	EP	Yes	GS-0098-024 GS-0098-026 GS-0098-028	No
o Crop 2 (Clover - Fresh and Hay)				
— Crop Field Trials	TEP	Yes	GS-0098-024 GS-0098-026	No
— Processed Food/Feed	EP	Yes	GS-0098-024 GS-0098-026	No

^{1/} Composition: TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than 48 months.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.125 Residue Chemistry</u> (Continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
o Crop 3 (Wheat - Grain)				
— Crop Field Trials	TEP	Yes	GS-0098-024 00086433	No
— Processed Food/Feed	EP	No	-	No ^{3/}
- Crop Group #6 - (Forage, Fodder and Straw of Cereal Grains Group)				
o Crop 1 (Barley Forage and Straw)				
— Crop Field Trials	TEP	Yes	GS-0098-024	No
— Processed Food/Feed	EP	Yes	GS-0098-024	No
o Crop 2 (Field Corn Forage and Fodder)				
— Crop Field Trials	TEP	Yes	GS-0098-024 GS-0098-025 GS-0098-026	No
— Processed Food/Feed	EP	Yes	GS-0098-024 GS-0098-025 GS-0098-026	No

^{1/} Composition: TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than 48 months.

^{3/} Since there are no detectable residues in grain, no residues are expected in the milled products of wheat.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/3/}
<u>\$158.125 Residue Chemistry</u> (Continued)				
171-4 - Magnitude of the Residue-Residue Studies (continued)				
o Crop Group #8 - (Miscellaneous Crops)				
o Crop 1 (Flaxseed)				
— Crop Field Trials	TEP	Yes	GS-0098-024 GS-0098-026	No
— Processed Food/Feed	EP	Yes	GS-0098-024 GS-0098-026	No
o Crop 2 (Safflower Seed)				
— Crop Field Trials	TEP	Yes	GS-0098-024 GS-0098-026	No
— Processed Food/Feed	EP	Yes	GS-0098-024 GS-0098-026	No
o Crop 3 (Barley-Legume and Flax-Legume Mixtures)				
— Crop Field Trials	TEP	No	—	No ^{3/}
— Processed Food/Feed	EP	No	—	No ^{3/}

^{1/} Composition: TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than 48 months.

^{3/} Data are not required unless the registrant wishes to establish a group tolerance for non-grass animal feeds or to establish a crop group tolerance for the foliage of legume vegetables.

TABLE B
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.120 Product Chemistry</u>				
<u>Product Identity:</u>				
61-1 - Identity of Ingredient	MP	Yes	GS-0098-019 GS-0098-020 GS-0098-021 GS-0098-022 GS-0098-023	No
61-2 - Statement of Composition Ingredients	MP	Yes	GS-0098-019 GS-0098-020 GS-0098-021 GS-0098-022 GS-0098-023	No
61-3 - Discussion of Formation of Ingredients	MP	Yes	00086414	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis	MP	No	-	Yes
62-2 - Certification of Limits	MP	No	-	Yes
62-3 - Analytical Methods for Enforcement of Limits	MP	No	-	Yes
<u>Physical and Chemical Characteristics</u>				
63-2 - Color	MP	Yes	GS-0098-020 00086414 00086391	No

^{1/} Composition: TGA1 = technical grade of the active ingredient.

^{2/} Data must be submitted no later than 6 months.

TABLE B
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>§158.120 Product Chemistry (continued)</u>				
63-3 - Physical State	MP	Yes	GS-0098-025 00086414 00086391	No
63-4 - Odor	MP	No	-	Yes
63-7 - Density, Bulk Density, or Specific Gravity	MP	Yes	GS-0098-024 00086414 00086391	No
63-12 - pH	MP	No	-	Yes
63-14 - Oxidizing or reducing action	MP	No	-	Yes
63-15 - Flammability	MP	No	-	Yes
63-16 - Explodability	MP	No	-	Yes
63-17 - Storage Stability	MP	No	-	Yes
63-18 - Viscosity	MP	No	-	Yes
63-19 - Miscibility	MP	No	-	Yes
63-20 - Corrosiveness	MP	No	-	Yes
<u>Other Requirements</u>				
64-1 - Submittal of Samples	Choice	No	-	Deferred ^{3/}

^{1/} Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

^{2/} Data must be submitted no later than 6 months.

^{3/} The Agency may request samples at a later date.

TABLE B
GENERIC DATA REQUIREMENTS FOR CHEMICAL DIALATE

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.27 Toxicology</u>				
<u>ACUTE TESTING:</u>				
81-1 - Oral LD ₅₀ - Rat	MP	Yes	00086378 00086441 00050737	No
81-2 - Dermal LD ₅₀	MP	Yes	00086379 00086440	No
81-3 - Inhalation LC ₅₀ - Rat	MP	Yes	-	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00086380 00086440	No
81-5 - Primary Dermal Irritation	MP	Yes	00086381 00086440	No
81-6 - Dermal Sensitization	MP	No	-	Yes

^{1/} Composition: MP = Manufacturing-use product.

^{2/} Data must be submitted within 48 months.

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER
FIFRA § 3(c)(2)(B)

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than 6 months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(B)."

In some cases Table B may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, you must comply with FIFRA Section 3(c)(1)(D). See Section III of this guidance document.

VI. LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you must submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR 162.11(c)], packaging [40 CFR § 162.16], and labeling [40 CFR § 162.1], as indicated by the following paragraphs of this section of the guidance document. The labeling must be submitted within 6 months of your receipt of this guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel the registration under FIFRA § 6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. **PRODUCT NAME** - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. **COMPANY NAME AND ADDRESS** - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. **NET CONTENTS** - A net contents statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26

ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR \$162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR \$162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR \$162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage of weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40 CFR \$162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations.

<u>Size of Label on Front Panel in Square Inches</u>	<u>Signal Word as Re- quired Minimum Type Size All Capitals</u>	<u>"Keep out of Reach of Chil- dren" as Required</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach Of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR 162.10(h)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR 162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity Category I on the basis of oral, inhalation or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix VI-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR 162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix VI-1. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. See Appendix VI-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

- a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.
- b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.
- c. A "non-flammable aerosol" is one which meets the following criteria:
 - i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii).
 - ii. There is no flash back; and
 - iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements may address hazards of explosivity oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Appendix VI-1 [40 CFR \$162.10(1)(2)(ii)]

Item 10A. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix VI-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-1. [40 CFR \$162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VII. Instructions for Submission

All applications prepared in response to this Notice should be addressed as follows:

Robert J. Taylor
Phone No. (703) 557-1800
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

- A. For each manufacturing-use product for which continued registration is desired:
1. Within 90 days from receipt of this document you must submit the "FIFRA Section (3)(c)(2)(B) Summary Sheet." Refer to Appendix IV-2(a) with appropriate attachments.
 2. Within 6 months from receipt of this document registrants must submit:
 - a. "Application for Amended Pesticide Registration" (EPA Form 8570-1).
 - b. "Confidential Statement of Formula" (EPA Form 8570-4).
 - c. "Data Compensation Statement: Reregistration." Refer to Appendix III-1(a).
 - d. Product Specific Data Report (Appendix III-2).
 - e. Two copies of any required product-specific data.
 - f. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this guidance document and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be either typewritten text on 8-1/2 x 11 paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.
 3. Within the time set forth in Table A, all generic data must be submitted by the affected registrants.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

- B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit:
1. The "FIFRA Section 3 (c)(2)(B) Summary Sheet" (Appendix IV-2) with appropriate attachments, and
 2. The "Data Compensation Statement: Reregistration." Refer to Appendix III-1(b).

DATA COMPENSATION STATEMENT: REREGISTRATION (MUPs)

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address _____

Date of application for reregistration: _____

Registration Standard for products containing: _____

Date Reregistration Guidance Document Issued: _____
In connection with applicant's application for
reregistration under the Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All generic data which, according to the Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product; and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application; and

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated: _____

Name of registrant's
authorized representative: _____

(Signature)

(Typed)

DATA COMPENSATION STATEMENT: REREGISTRATION (End-Use Products)

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address: _____

Date of application for reregistration: _____

Registration Standard for products containing: _____

Date registration Guidance Document Issued: _____

Registrant offers to pay compensation to other persons for the data listed in Table A to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registrant has furnished offers to pay compensation to the persons identified in Table A and in the form specified by the Guidance Document.

Dated: _____

Name of registrant's
authorized representative: _____

(Signature)

(Typed)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No. _____ Guidance Document for _____

Date: _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with Data Requirements by Submitting Data (attached)	(For EPA Use Only) Accession Numbers Assigned
163.61-3	Product identity and disclosure of ingredients			
-4	Description of manufacturing process			
-5	Discussion on formation of unintentional ingredients			
-6	Declaration and certification of ingredient limits			
-7	Product analytical methods and data			
163.61-8(1)	Color			
-8(2)	Odor			
-8(3)	Melting Point			
-8(4)	Solubility			
-8(5)	Stability			
-8(6)	Octanol/water partition coefficient			
-8(7)	Physical state			
-8(8)	Density or specific gravity			
-8(9)	Boiling point			
-8(10)	Vapor pressure			
-8(11)	pH			
-8(12)	Storage stability			
-8(13)	Flammability			
-8(14)	Oxidizing or reducing action			
-8(15)	Explosiveness			
-8(16)	Miscibility			
-8(17)	Viscosity			
-8(18)	Corrosion characteristics			
-8(19)	Dielectric breakdown voltage			
163.71-5(1)	Cage or pen field test			
-5(2)	Full scale field test			
163.72-1	Fish acute LC ₅₀ rainbow trout and bluegill			
163.72-2	Acute toxicity to aquatic invertebrates			
-3	Acute toxicity to estuarine and marine organisms			
-6(a) (1)	Short term simulated field tested			
-6(a) 2	Long term simulated field tested			
163.81-1	Acute oral toxicity			
-2	Acute dermal toxicity			
-3	Acute inhalation toxicity			
-4	Primary eye irritation			
-5	Primary dermal irritation			
-6	Dermal sensitization			

Guide to Use of This Bibliography

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant to EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature in those instances where they have been considered, will be included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MIRD), each entry consists of a citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standard Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.
 - b. **Document Date.** When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
- (1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.
 - (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter, following the phrase "submitted by," When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers).
The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second 123456-B; the 26th 123456-Z; and the 27th 123456-AA.

- 00002536 Grover, R. (1974) Adsorption and desorption of Trifluraline, Triallate, and Diallate by various adsorbents. Weed Science 22(4):405-408. (Also in unpublished submission received on unknown date under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:221991-C)
- 00017802 U.S. Department of Health, Education, and Welfare (1969) Report of the Secretary's Commission of Pesticides and Their Relationship to Environmental Health. Washington, DC: U.S. Government Printing Office. (pp. 461-495, 655-577 only; available from: U.S. G.P.O, Washington, D.C.; 0-371-074; also in unpublished submission received Mar 17, 1976 under 38329-2; submitted by Consolidated Chemical Co., Denver, Colo.; CDL:225259-Q)
- 00021823 Gray, R.A. (19??) Behavior, Persistence & Degradation of Carbamate and Thiocarbamate Herbicides in the Environment. (Unpublished study received Mar 27, 1972 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-B)
- 00028956 Salamon, C.; Smith, S.; Arceo, R.J.; et al. (1979) Final Report to Monsanto Company: Three-Generation Reproduction Study with Avadex Herbicide in Albino Rats: IBT No. 623-06841. (Unpublished study including letters dated Feb 15, 1980 from R.W. Street to F.C. Meyer and Feb 25, 1980 from M.S. Weinberg to F.C. Meyer, received Feb 28, 1980 under 524-110; prepared in cooperation with Booz, Allen & Hamilton, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:241935-F)
- 00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honeybees: Laboratory Studies. By University of California, Dept. of Entomology. UC, Cooperative Extension. (Leaflet 2287; published study.)
- 00046243 Phillips, B.M.; Reinart, D.; Fletcher, D.; et al. (1977) Final Report to Monsanto Company: 42-Day Neurotoxicity Study with Diallate in Chickens: IBT No. 8580-10813. (Unpublished study including letter dated Mar 27, 1980 from M.S. Weinberg to Arthur Uelner, received May 7, 1980 under 524-119; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:242484-A)
- 00050252 Kay, J.H. (1959) Report to Monsanto Chemical Company: Subacute Oral Toxicity of CP 15336--Dogs. (Unpublished study received Apr 1, 1977 under 524-119; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:229217-A)
- 00050737 Harrison, W.A. (1976) Report to Monsanto Company: Acute Oral Cholinesterase Activity Studies with 5 Samples: CP 41834 (Glyphosine), CP 4742 (Vegadex), CP 15336 (Avadex) CP 23426 (Avadex BW) and CP 15938 (Carbaryl) in Albino Rats: IBT No. 8530-09030. (Unpublished study received May 19, 1977 under 524-311; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:230339-E)

- 00068699 Rummens, F.H.A.; Louman, F.J.A. (1970) Proton magnetic resonance spectroscopy of thiocarbamate herbicides. Journal of Agricultural and Food Chemistry 18(6):1161-1164. (Also in unpublished submission received Jun 23, 1977 under 476-2182; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:230714-E)
- 00073505 Cliffe, E.E.; Watkins, T.I. (1961) The Metabolic Fate of 14-C Labelled Avadex in the Rat: Report No. 1164. (Unpublished study received Jul 8, 1970 under unknown admin. no.; prepared by Boots Pure Drug Co., Ltd., submitted by Monsanto Co., Washington, D.C.; CDL:108444-C) .
- 00083644 (GS-0098-002) Brunsick, D.J. (1977) Mutagenicity Evaluation of CP 23426 in the Mouse Lymphoma Assay: LBI Project No. 2684. Final rept. (unpublished study received on March 22, 1978) prepared by Litton Bionetics, Inc., submitted by Monsanto Co. CDL: 233353
- 00086378 Braun, W.G.; Rinehart, W.E. (1979) Acute Oral Toxicity Study in Rats: Project No. 4931-77; BDN-77-441. Rev. (Unpublished study, including letter dated Aug 6, 1979 from W.E. Rinehart to George Levinskas, received Oct 16, 1979 under 524-119; prepared by Bio/dynamics, Inc., submitted by Monsanto Co., Washington, D.C.; CDL:241270-M)
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- 00086389 Monsanto Company (1956?) General Description of the Chemical Method for the Fujiwara Reaction. (Unpublished study received May 12, 1964 under 9F0832; CDL:093534-D)
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- 00086391 Monsanto Company (19??) The Name, Chemical Identity, Physical Composition of the Pesticide Chemical: [Avadex]. (Unpublished study received May 12, 1964 under 9F0832; CDL:093534-F)

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- 00086410 Monsanto Company (1959) Results of Tests on the Amount of
Residue Remaining, Including a Description of the Analytical
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1960 under unknown admin. no.; CDL:121072-B)
- 00086414 Monsanto Company (1977) The Name, Chemical Identity, Physical
Composition of the Pesticide Chemical: [Avadex-Technical].
(Unpublished study received Dec 11, 1972 under 524-306;
CDL:101433-A)
- 00086416 Monsanto Company (1959) Results of Tests on the Amount of
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Methods Used: [Avadex]. (Unpublished study received Mar 7,
1960 under unknown admin. no.; CDL:120781-B)
- 00086417 Monsanto Company (1977) [Chromatographs of Avadex].
(Compilation; unpublished study received Dec 5, 1978 under
524-119; CDL:236540-A)
- 00086421 Hunt, C.R.; Conkin, R.A. (1964) Results of Tests on the Amount
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Analytical Methods Used. Includes undated methods entitled:
The determination of residues of Avadex in mature sugar
beets by column and gas-liquid chromatography; The
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residues of Avadex in soils. (Unpublished study received
Jan 27, 1965 under 524-110; submitted by Monsanto Co.,
Washington, D.C.; CDL:003965-C)
- 00086425 Conkin, R.A.; Selleck, G.W.; Hannah, L.H. (1961) Results of
Tests on the Amount of Residue Remaining, Including a
Description of the Analytical Methods Used: [Avadex].
Includes undated methods : Diisopropylamine-methyl orange
complex. (Unpublished study received Dec 27, 1961 under
524-119; submitted by Monsanto Co., Washington, D.C.;
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- 00086429 Monsanto, Company (1961) Results of Tests on the Amount of
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- 00086432 Wolvin, A.A. (1968) Report to Monsanto Company: Quail Toxicity
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- 00086440 Younger, F.M. (1959) Toxicology Investigation of CP 15336--2,3-Dichloroallyl Diisopropylthiocarbamate: Monsanto Project No. Y-59-34. (Unpublished study received Apr 1, 1960 under 524-119; prepared by Younger Laboratories, submitted by Monsanto Co., Washington, D.C.; CDL:003959-H)
- 00086441 Younger, F.M. (1959) The Acute Oral Toxicity (LD50) of CP-15336--2,3-Dichloroallyl Dissopropylthiocarbamate for Dogs: Monsanto Project No. Y-59-37. (Unpublished study received Apr 1, 1960 under 524-119; prepared by Younger Laboratories, submitted by Monsanto Co., Washington, D.C.; CDL:003959-I)
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Appendix IV-2(a)

FIFRA § 3(c)(2)(B) SUMMARY SHEET

EPA Registration No.: _____
Product Name: _____
Applicant's Name: _____
Date Guidance Document Issued: _____

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner.

1. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:
2. ☐ I have entered into an agreement with one or more other registrants under FIFRA § 3 (c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).
3. ☐ I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements: (attached).
4. ☐ I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):
5. ☐ I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Dated: _____

Registrant's authorized
representative:

(signature)

(typed)

CERTIFICATION OF ATTEMPT TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA
(TO QUALIFY, CERTIFY ALL FOUR ITEMS)

- (1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated _____ to submit data concerning the active ingredient _____:

Name of Firm

EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

- (2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:
- (3) My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm

Date of Offer

However, none of those firm(s) accepted my offer.

- (4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

Dated: _____

(Signature)

(Typed)

cc: A copy of the offer(s) is attached.

TABLE D
LABELING REQUIREMENTS OF THE FIFRA

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front Panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc.
3	Net contents	All Products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.

APPENDIX VI-2 (continued)

TABLE 2

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7B	Signal word	All products	Front Panel	Immediately below child hazard warning	Note type size requirements.
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		

TABLE F-1

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	REFERRED	COMMENTS
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	

TABLE P-2

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be grouped together, and preferably blocked. Heading must be same type size as child hazard warning.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

Appendix VI-3

PHYSICAL-CHEMICAL HAZARDS

<u>Criteria</u>	<u>Required Label Statement</u>
-----------------	---------------------------------

I. Pressurized Containers

- | | |
|---|---|
| A. Flash point at or below 20°F; or if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening. | Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture; or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| C. <u>ALL OTHER PRESSURIZED CONTAINERS</u> | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |

II. Non-Pressurized Container

- | | |
|---|--|
| A. Flashpoint at or below 20°F. | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| B. Flashpoint above 20°F and over 80°F | Flammable. Keep away from heat and open flame. |
| C. Flashpoint over 80°F and not over 150°F. | Do not use or store near heat and open flame. |
| D. Flashpoint above 150°F. | None required. |

STORAGE INSTRUCTIONS FOR PESTICIDES

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to staking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas

(continued)

PROPOSED DISPOSAL STATEMENTS
FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all) - Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash collection.
2. Metal (all sizes) - Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill or by other approved State and local procedures.
3. Plastic (all) - Triple rinse (equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill or by incineration if approved State and local authorities.
4. Glass (all) - Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.
5. Fiber drums with liners - Dispose of liners according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.
6. Paper and plastic bags - Dispose of bags according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act.
7. Compressed gas cylinders - Return empty cylinder for reuse (or similar wording).

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.

(continued)

PROPOSED DISPOSAL STATEMENTS
FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all) - Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash collection.
2. Metal (all sizes) - Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill or by other approved State and local procedures.
3. Plastic (all) - Triple rinse (equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill or by incineration if approved State and local authorities.
4. Glass (all) - Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.
5. Fiber drums with liners - Dispose of liners according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.
6. Paper and plastic bags - Dispose of bags according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act.
7. Compressed gas cylinders - Return empty cylinder for reuse (or similar wording).

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.